DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 23, 2014

Oticon Medical AB
Ms. Carolina Wessling
Quality Assurance and Regulatory Affairs Manager
Ekonomivägen 2
SE-436 33, Askim,
SWEDEN

Re: K141616
Trade/Device Name: Sterilization Cassette
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Cassette
Regulatory Class: II
Product Code: KCT
Dated: August 14, 2014
Received: August 19, 2014

Dear Ms. Wessling:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known):___K141616_____

Device Name: Sterilization Cassette

Indications for Use:

The Oticon Medical Sterilization Cassette is intended to organize and protect non-disposable medical device instrumentation during handling and use in hearing health care surgery. It is intended to be sterilized and stored with non-disposable medical device instrumentation. The Sterilization Cassette is intended to be used in conjunction with a legally marketed sterilization wrap in order to maintain sterility of the enclosed instruments until use.

The sterilization cassette is intended for washing, either manually or in an automated process in a washer disinfector, and for sterilization in a pre-vacuum steam sterilizer (min. three pulse, standard) utilizing either of the following cycles:

	Cycle alt 1	Cycle alt 2	Cycle alt 3
Temperature	132˚C (270°F)	134˚C (273°F)	135˚C (275°F)
Exposure time	4 Minutes	3 Minutes	3 Minutes
Drying time (wrapped)	20 Minutes	16 Minutes	16 Minutes

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use __X___ (21 CFR 801 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

09.12.2014

510(k) SUMMARY

Sterilization Cassette

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Submitter name:	Oticon Medical AB
Address:	Ekonomiv. 2 SE-436 33 Askim Sweden
Phone: Facsimile:	+46 31 748 6100 +46 31 687 756
Contact Person: Mobile phone:	Carolina Anker Wessling +46 761 68 63 32
Date Prepared:	September 12, 2014

Name of Device and Name/Address of Manufacturer

Sterilization Cassette

Oticon Medical AB
Ekonomiv. 2
SE-436 33 Askim
Sweden

Common or Usual Name: Sterilization Cassette

Classification Name: Sterilization wrap, containers, trays, cassettes and other accessories

Classification: Class II

Classification Regulation: 21 CFR 880.6850 (Product code KCT)

Predicate Devices:

Device	510(k) no.	Manufacturer
Hu-Friedy IMS Cassette System	K844002	Hu-Friedy Mfg. Co., Inc.
PolyVac Surgical Instrument Delivery System	K012105	Symmetry Medical, Inc.

Intended Use / Indications for Use

The Oticon Medical Sterilization Cassette is intended to organize and protect non-disposable medical device instrumentation during handling and use in hearing health care surgery. It is intended to be sterilized and stored with non-disposable medical device instrumentation. The Sterilization Cassette is intended to be used in conjunction with a legally marketed sterilization wrap in order to maintain sterility of the enclosed instruments until use.

The sterilization cassette is intended for washing, either manually or in an automated process in a washer disinfector, and for sterilization in a pre-vacuum steam sterilizer (min. three pulse, standard) utilizing either of the following cycles:

	Cycle alt 1	Cycle alt 2	Cycle alt 3
Temperature	132˚C (270°F)	134˚C (273°F)	135˚C (275°F)
Exposure time	4 Minutes	3 Minutes	3 Minutes
Drying time (wrapped)	20 Minutes	16 Minutes	16 Minutes

Device Description / Technological Characteristics

The Oticon Medical Sterilization Cassette is a stainless steel cassette consisting of a base tray, a lid and an insert with instrument holders made of silicone. The lid is locked to the base tray by a locking tab. Once the lid is closed and locked, enclosed instruments are kept in place by the holders and a silicone rail in the lid.

The Sterilization Cassette is designed using materials that can be reused with steam sterilization methods. The base tray, lid and insert have evenly distributed perforations to allow for penetration of sterilant during steam sterilization. For the sterilization process, the cassette is to be used in conjunction with a legally marketed sterilization wrap.

Performance Data

Testing of the Oticon Medical Sterilization Cassette includes (1) verification of automated cleaning and disinfection, (2) verification of manual and ultrasonic cleaning, (3) sterilization validation, and (4) testing for wear following re-use and repeated processing.

The testing demonstrated efficiency of the cleaning and disinfection procedures, and the sterilization tests showed that under the selected processing parameters excellent steam penetration was achieved within the wrapped cassettes. Sterilization testing further demonstrated a sterility assurance level (SAL) of 10^{-6} of the cassette and its contents when handled according to the recommended instructions.

In all instances, the Sterilization Cassette functioned as intended and the performance observed was as expected. Hence we have come to the conclusion that further testing will not raise new issues of safety or efficacy.

Substantial Equivalence

The Oticon Medical Sterilization Cassette was compared to the predicate devices Hu-Friedy IMS Cassette System (K844002) and PolyVac Surgical Instrument Delivery System (K012105) by review of intended use and technological characteristics, e.g. product design, device characteristics and materials.

The Oticon Medical Sterilization Cassette is comparable in design to the predicate device sterilization cassettes and has the same intended use/indications, as well as principles of operations. The minor technological differences between the Oticon Medical Sterilization Cassette and the predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that the Oticon Medical Sterilization Cassette is as safe and effective as the predicate device. Thus, the Oticon Medical Sterilization Cassette is substantially equivalent.

Comparison Table for Substantial Equivalence

	Proposed device	**Predicate device**	**Predicate device**
Product name (510(k) number)	Sterilization Cassette (K141616)	PolyVac Surgical Instrument Delivery System (K012105)	Hu-Friedy IMS Cassette System (K844002)
Manufacturer	Oticon Medical AB	Symmetry Medical, Inc.	Hu-Friedy Mfg. Co., Inc.
Intended Use / Indications for use	The Oticon Medical Sterilization Cassette is intended to organize and protect non-disposable medical device instrumentation during handling and use in hearing health care surgery. It is intended to be sterilized and stored with non-disposable medical device instrumentation. The Sterilization Cassette is intended to be used in conjunction with a legally marketed sterilization wrap in order to maintain sterility of the enclosed instruments until use. The sterilization cassette is intended for washing, either manually or in an automated process in a washer disinfector, and for sterilization in a pre-vacuum steam sterilizer (min. three pulse, standard) utilizing either of the following cycles: Temperature 132˚C (270°F) –	PolyVac's delivery systems are intended to protect medical device instrumentation and to facilitate the sterilization process by allowing steam penetration and air removal. When used in conjunction with an approved sterilization wrap, sterility of the enclosed medical device is maintained until used. PolyVac's delivery systems are to be sterilized in one of the following cycles: Prevacuum Steam: 132ºC – 4 minutes minimum. Dry for 20-40 minutes as needed Gravity Steam: 132ºC – 30 minutes minimum. Gravity Steam: 121ºC – 55 minutes minimum. Dry for 20-50 minutes as needed.	The Instrument Management System is designed to provide a disciplined approach to infectious disease control while helping achieve greater efficiency and cost-effectiveness in the care and maintenance of dental instruments. The IMS Cassettes are the core of the system. The cassettes can be sterilized by steam, chemical vapor, ethylene oxide, or dry heat. *As extracted from IMS Operator's Manual.*

	Exposure time 4 minutes – Dry for 20 minutes. Temperature 134˚C (273°F) – Exposure time 3 minutes – Dry for 16 minutes. Temperature 135˚C (275˚F) – Exposure time 3 minutes – Dry for 16 minutes		
Device description	• Base, tray and lid • Evenly distributed perforated hole pattern. • Silicone holders/rail	• Base, modular insert trays and lids • Evenly distributed perforated hole pattern. • Silicone mats	• Base, modular insert trays and lids. • Evenly distributed perforated hole pattern. • Silicone rails
Dimensions (l x w x h)	Cassette outer dimensions 180 x 140 x 42 mm *(approx 7.1 x 5.5 x 1.7 inches)*	Base tray 17.3 x 7.25 x 4 inches	Available in over 100 different sizes, configurations and color options.
Materials	Stainless steel, silicone	Stainless steel, Aluminium, Radel R plastic, silicone	Stainless steel, silicone
Sterilant penetration	Evenly distributed hole pattern	Evenly distributed hole pattern	Evenly distributed hole pattern
Microbial barrier properties	For the sterilization process, the cassette is to be used in conjunction with a legally marketed sterilization wrap.	To be used in conjunction with an approved sterilization wrap.	To be used together with IMS Autoclave Wrap.
Pre-Vac Steam Sterilization parameters, including drying time	Pre-vacuum steam sterilizer (min. three pulse, standard) utilizing either of the following cycles: Temperature 132˚C (270°F) – Exposure time 4 minutes – Dry for 20 minutes. Temperature 134˚C (273°F) – Exposure time 3 minutes – Dry for 16 minutes. Temperature 135˚C (275˚F) – Exposure time 3 minutes – Dry for 16 minutes	Prevacuum Steam: 132ºC – 4 minutes minimum. Dry for 20-40 minutes as needed	Follow sterilizer manufacturer's directions for "wrapped instruments" to determine length of cycle, temperature and drying instructions.
Material compatibility with sterilization process	Yes	Yes	Yes
Reusable	Yes	Yes	Yes